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Paper 7
Entered: February 11, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.,
Petitioner,

v.

CELGENE CORP.,
Patent Owner.

Case IPR2018-01507
Patent 8,404,717 B2

Before GRACE KARAFFA OBERMANN, TINA E. HULSE, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Dr. Reddy's Laboratories, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet."), requesting institution of an *inter partes* review of claims 1–10 of U.S. Patent No. 8,404,717 B2 (Ex. 1001, "the '717 patent"). Celgene Corp. ("Patent Owner") timely filed a Preliminary Response (Paper 6, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that Petitioner has not demonstrated sufficiently that certain press releases relied upon in its patentability challenges qualify as printed publications. We thus decline to institute an *inter partes* review of claims 1–10 of the '717 patent.

A. *Related Proceedings*

"Petitioner is not aware of any reexamination certificates or pending prosecution concerning the '717 patent" and "is not aware of any prior petitions for *inter partes* review related to the '717 patent." Pet. 49. Petitioner is a defendant in the following litigation involving the '717 patent: *Celgene Corp. v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Case No. 2:17-cv-05314-SDW-LDW (D.N.J.) ("the Celgene litigation"). *Id.*

Patent Owner confirms that the '717 patent "is not at issue in any other *inter partes* review or *inter partes* reexamination proceedings." Paper 4, Section II.A (Patent Owner's mandatory notice, containing no page numbers, but identifying related matters in Section II.A–II.C). Like

Petitioner, Patent Owner identifies the Celgene litigation as a related matter. *Id*. at Section II.C. Patent Owner also identifies as related matters Case IPR2018-01504 (IPR504) and Case IPR2018-01509 (IPR509), which involve the same parties but different challenged patents.[1] *Id*. at Section II.B. In addition, Patent Owner identifies one "pending" and two "no longer pending" litigations involving the '717 patent in which Petitioner is not, or was not, a party. *Id*. at Section II.C.

B. *The '717 Patent (Ex. 1001)*

The '717 patent issued on March 26, 2013, and claims priority to application No. 11/654,550, filed on January 16, 2007. *See* Ex. 1001, Title Page. It names Jerome B. Zeldis as the sole inventor. *Id.*

The '717 patent discusses methods of treating, preventing and/or managing myelodysplastic syndromes ("MDS") by methods of administration of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidin-2,6-dione (lenalidomide) in combination with 5-azacitidine. *Id.*, Title, Abstract. The '717 patent identifies lenalidomide, also known by its commercial name as Revimid, as an immunomodulatory compound to be used in such treatment methods. *Id.* at 1:23–29.

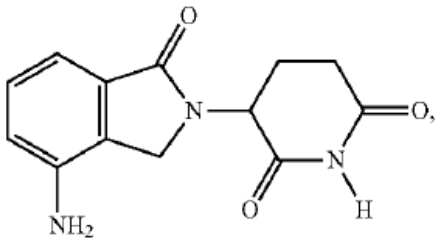
C. *Illustrative Claim*

Claim 1 is the only independent claim. Claim 1 is illustrative of the claimed subject matter and reproduced below:

> 1. A method of treating a patient having transfusion dependent anemia due to low to intermediate-1-risk myelodysplastic syndrome, which comprises administering to said patient in need thereof about 5

[1] Concurrently with this decision, the Board issues decisions denying institution in IPR504 and IPR509 based on substantially the same analysis set forth in this decision.

to about 25 mg per day of 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidin-2,6-dione having the formula:



or a pharmaceutically acceptable salt, solvate or stereoisomer thereof.

Ex. 1001, 27:26–28:11.

D. *Asserted Grounds of Unpatentability*

Petitioner challenges the patentability of the claims of the '717 patent on the following grounds:

Reference(s)	Basis	Claims Challenged
List 2001,[2] '230 patent,[3] Celgene Press Release 5/8/2001,[4] and Celgene Press Release 8/28/2001[5]	§ 103(a)	1–10

[2] Richard J. Klasa, Alan F. List, and Bruce D. Cheson, *Rational Approaches to Design of Therapeutics Targeting Molecular Markers*, HEMATOLOGY 443 (2001) (Ex. 1004).

[3] U.S. Patent No. 6,281,230 B1 (Ex. 1006).

[4] Press Release, Celgene Corp., *Positive Interim Results Presented at the VIIIth International Myeloma Workshop on Celgene Corporation's Lead IMiD(TM) (REVIMID(TM))* (May 8, 2001) (on file with PR Newswire) (Ex. 1008).

[5] Press Release, Celgene Corp., *Celgene Corporation Awarded Additional Patent Protection For Lead IMiD(TM), REVIMID(TM): Comprehensive Patent Protection for REVIMID Includes Coverage of the Active Ingredient, Pharmaceutical Compositions, and Therapeutic Uses* (Aug. 28, 2001) (on file with PR Newswire) (Ex. 1010).

Reference(s)	Basis	Claims Challenged
Thomas 2000a,[6] '230 patent, Celgene Press Release 5/8/2001, and Celgene Press Release 8/28/2001	§ 103(a)	1–10

II. ANALYSIS

A. *Claim Construction*

We interpret claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b) (2016)[7]. Under that standard, claim terms are given their ordinary and customary meaning in view of the specification, as understood by a person of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). We resolve disputed claim terms only to the extent necessary to our decision. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

The Petition does not assert that any claim term requires express construction and states that "one of ordinary skill in the art would

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[6] Deborah A. Thomas, MD and Hagop M. Kantarjian, MD, *Current Role of Thalidomide in Cancer Treatment*, 12 CURRENT OP. IN ONCOLOGY 564 (2000) (Ex. 1005).

[7] A recent amendment to this rule does not apply here, because the Petition was filed before November 13, 2018. *See* "Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board," 83 Fed. Reg. 51,340 (Oct. 11, 2018) (to be codified at 37 C.F.R. pt. 42).

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